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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,843	07/28/2003	Leonard S. Schultz	6971.02	5820

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,843

Applicant(s)

SCHULTZ, LEONARD S.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 11 September 2006.
2. Examiner acknowledges the changes made to the abstract and specification, as well as the enclosed non-patent literature disclosed in the IDS submitted on 10 January 2005.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 29 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **5,292,332**) in view of **Clark et al.** (U.S. Patent No. **5,259,835**).

Claim 29: Lee discloses a plug **22** and a delivery instrument **34** detachably coupled to the plug **22** for moving to a selected location (Figure 1 and col. 4, lines 49-51 and col. 5, lines 42-46) and a biological bonding agent **57**. Lee discloses the claimed device except for the plug **22** having a plurality of openings through which the biological bonding agent is moved.

Clark et al. teaches a wound closure device **36** having a plurality of openings into which a biological bonding agent permeates (col. 3, lines 47-50). Clark et al. teaches that the porous structure of the device serves as a matrix for the adhesive (col. 3, lines 51-53). It would have been obvious to one of ordinary skill in the art to add a plurality of openings, as taught by Clark et al., to the device of Lee, in order to provide a suitable bonding material, or matrix, for the biological bonding agent.

Claim 34: Lee discloses a device with a plugging means **22** adapted for occluding a body lumen and a delivery means **34** that is detachably coupled to the plugging means (see explanation for Claim 29 above). Lee discloses inserting the device adapted for occluding a body lumen with the plugging means entering the puncture orifice **24** ("lumen") first and advancing the device to a target site (Figure 4 and col. 5, lines 24-31). Lee discloses detaching the delivery means **34** from the plugging means **22** and withdrawing the delivery means **34** from the puncture orifice **24**, leaving the plugging means **22** inside the puncture orifice **24** (Figure 6, col. 5, lines 42-26).

Lee discloses the claimed device except for the plugging means having a plurality of openings, injecting a biphasic material into the delivery means and conveying the biphasic material to the plugging means, and moving the biphasic material through the openings of the plugging means to fix the plugging means relative to the interior wall of the body lumen.

Clark et al. teaches the plurality of openings through which the biological bonding agent is moved (see explanation for Claim 29 above). Clark et al. teaches the injection of biphasic material **57** through a delivery means **34** and conveying it into a bonding pad

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36 ("plugging means") and wherein the biphasic material **57** moves through the openings of the bonding pad **36**, and is adapted to be fixed to the interior of a body lumen (col. 4, lines 3-21). It would have been obvious to provide a plurality of openings, and therefore the injecting and moving of the biphasic material steps, as taught by Clark et al., to the device of Lee, in order to provide a suitable bonding material, or matrix for the biological bonding agent (see explanation for Claim 29 above).

5. Claims 30-33 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **5,292,332**) and **Clark et al.** (U.S. Patent No. **5,259,835**), as applied to Claims 29 and 34 above, and further in view of **Wallace et al.** (U.S. Patent No. **6,585,754**).

Claims 30-33 and 35-37: Lee and Clark et al. disclose the claimed device except for the bonding agent comprising a biphasic material, a biosorbable material, a shape memory material, and the biphasic material being biosorbable and a shape memory material.

Wallace et al. teaches the use of biphasic material and biosorbable material (col. 4, lines 48-57) and shape memory material (col. 4, lines 41-45), wherein the the biosorbable and shape memory materials are biphasic, in the art of vaso-occlusive members. Wallace et al. teaches that the use of these materials encourages greater tissue ingrowth, and therefore more stable occlusions (col. 4, lines 15-17). It would have been obvious to one of ordinary skill in the art to have the bonding agent comprise biphasic, biosorbable, and shape memory material, as taught by Wallace et al., to Lee

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and Clark et al., in order to provide greater tissue ingrowth and therefore a more stable occlusion in the body lumen.

Response to Arguments

6. Applicant's arguments filed 24 August 2006 have been fully considered but they are not persuasive.

7. Applicant argues that Lee teaches away from lumen occlusion in percutaneously sealing a puncture in an artery *without* impeding blood flow within the lumen. The examiner disagrees. Lee does not teach away from lumen occlusion, but rather teaches closing a puncture in a lumen though while still allowing some blood flow in the plug extending into the puncture and occluding the vessel, and therefore reads on the invention of Claims 29 and 34.

8. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, the motivation to combine the device of Clark, which is capable of occluding a body lumen, to Lee, is maintained in that a porous structure provides a matrix for an adhesive, and therefore holds the bonding agent to maintain its engagement with the wound closure.

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9. Applicant argues that there is no incentive to combine Wallace to Lee and Clark other than the mere fact that the implantable vaso-occlusive member in Wallace is made of absorbable material. However, the examiner maintains the position, as mentioned above, that it would have been obvious to one of ordinary skill in the art to provide the plugging means with a plurality of openings in the combined device of Lee and Clark with the biphasic, biosorbable, shape memory materials in the bonding agents, as taught by Wallace, in order to provide greater tissue ingrowth and a more stable occlusion in the lumen.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M. J. Hayes", is positioned above the printed name.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER